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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,854	01/25/2002	Alfred Schaufler	2002-0092A	8581

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,854	SCHAUFLER, ALFRED	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 03 May 2005.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) 35-40 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-34 and 41-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

REASSIGNMENT AFFECTING APPLICATION LOCATION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1654.**ACKNOWLEDGEMENT OF AMENDMENT, REMARKS, STATUS OF THE APPLICATION AND CLAIMS**

2. The amendment and remarks filed 05/03/05 are acknowledged, entered and considered. In view of Applicant's request claims 1, 5-12, 14-16, 18-30 and 34 have been amended and claims 41-44 have been added. Claims 1-44 are pending of which claims 35-40 are withdrawn. Thus, the Office action is directed to the merits of claims 1-34 and 41-44 as elected invention. It is suggested that Applicant cancel the none-elected (withdrawn) claims in the next communication. The objection to trademarks and the rejection under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendment and remarks filed 05/03/05. However, the rejection under 35 U.S.C. 103(a) over the prior art of record is maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. § 103(a)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-34 and newly submitted claims 41-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai Japanese Unexamined Patent Publication No. 7-59812 (Publication date 3/17/95) taken with GB Patent No. 1 292 326 and WO 99/13902.

Applicant's arguments filed 05/03/05 have been fully considered but they are not persuasive. Applicant has argued that the cited prior art references must teach or suggest all of the claims limitations set forth in the pending independent claims, particularly as currently amended in order to establish *prima facie* case of obviousness. The primary reference's JP No. 7-59812 discloses a method for producing a wound cover material in which a collagen sponge structure or body has a honey comb structure. Air bubbles are controlled to a diameter within the range 50-2,000 μm, which bubbles communicates from one surface to the other surface. Thus, the primary reference fails to disclose or suggest any method that would result in collagen sponge with a chamber structure with stacked chambers that are separated and substantially totally enclosed by walls of collagen material is unpersuasive. Contrary to Applicant's arguments, the primary reference teaches the use of a wound cover material comprised of a collagen sponge structural body having a so-called honeycomb structure that has air bubbles controlled to a diameter within the range of 50-2000 μm, (overlapping the claimed ranges claimed by Applicant), said air bubbles communicating straight from one surface to the other surface, and each of said air bubbles being substantially independent from each other. On page 5, the primary reference clearly shows that it is

within skill of the art to which this invention pertains to control the diameter of the air bubbles by regulating the amount of collagen and concentration of ammonia gas, thereby making it possible to change the pore size of the collagen sponge. Thus, the step of mixing air into collagen gel is expected to result a collagen sponge which has a three-dimensional structure with stacked chambers separated and substantially totally enclosed by walls of collagen materials as admittedly acknowledged on page 4, lines 17-20 in the instant specification as originally filed and as currently amended in independent claims 1 and 34. Because it is an inherent or expected property of the dried collagen obtained by a dry block of collagen sponge.

Applicant asserts that there is no reason for combining the secondary references with the primary reference because there is no indication that any improvement or benefit would be achieved by such consideration of the combination of the references is unpersuasive. Contrary to Applicant's assertion, the primary reference of the Japanese unexamined patent publication No. 7-59812 differs from claims 1-34 and newly submitted claims 41-44 in not teaching a) obtaining collagen from tendons having a sponge density of 1 to 10 mg/cm^3, b) use of or organic acids, and c) the selection of specific temperatures, pHs, viscosity, elasticity, and density. However, GB patent No. 1 292 326 teaches a method and apparatus for the preparation of collagen dispersions with a view of to their applications, wherein by "dispersion of collagen" is meant a normal or colloidal or gel of collagen in water or the relevant organic medium. The preparation of spongy collagenic articles can be effected from dispersion or gels of collagen by using lyophilization techniques. A sub-atmospheric pressure exists in the

treatment chamber, in which the suspension is transformed into a dispersion by stirring and controlled acidification by means of a mineral or organic acid such as lactic acid (See pages 1-3) as directed to claims 6, 7, 9 and 11. On example 2, the reference discloses a collagenic dispersion free of air bubbles having lactic acid content of 0.5%, collagen content of 2.5%, the density of the dispersion is 0.80 and its viscosity 37 poises at the sliding velocity of 5.5 sec^{-1} as directed to claims 11, 15, 17, 20-24 and 29. Furthermore, as acknowledged on page 3, lines 16 to 29, the reference of WO 99/1392 discloses the preparation of sponge from bovine tendons by dispersing at pH in the range of about 2 to 3 into a solvent such as lactic acid and mixing with a high level of agitation using a blender, so as to produce microfibers of collagen, and lyophilization of a collagen dispersion having sponge density of about 0.1 mg/cm^3 and a pore size ranges from about 10 μm to about 500 μm (See e.g., pages 7-8 and 10) as directed to claims 4-10 and 14-16.

In regard to specific pHs, temperatures, diameters, dimensions, percentage of collagen content, viscosity, duration of time for storage, homogenizing, neutralizing and drying, percentage of lactic acid, gel content, water content and others; the combined teachings of the prior art as shown above clearly discloses ranges which overlaps with claimed pHs, temperatures, diameters, dimensions, contents of collagen, gels, lactic acid, viscosity, and duration of times as recited in the claims. The prior does not disclose the specifics as claimed; however, the ranges disclosed in the prior art and claimed by Applicant overlap in scope, and as such it is conventional and within the skill of the art to optimize or select the specifics from the ranges disclosed. See *Ex parte*

Lee, 31 USPQ2d 1105 (Bd. Pat. App. & inter. 1993); also, See MPEP 2131.03. Further, it is conventional and within the ordinary skill in the art to which this invention pertains to determine the optimization values of causes effective variables such as these process parameters. Thus, the instant invention's method of preparing a collagen sponge, which falls within the scope of the combined teachings of the cited prior method of preparation of collagen sponge would have been *prima facie* obvious from said prior art combined disclosure to a person of the ordinary skill in the art because in the absence of sufficient objective factual evidence or unexpected results to the contrary, Applicant's claims are directed to optimization of an "art recognized variables" which is well within the purview of one of ordinary skill in the art, *In re Boesch*, 617 f. 2d 272, 205 USPQ 215 (CCPA 1980).

Therefore, it is made obvious by the combined teachings of the prior art since the instantly claimed invention which falls within the scope of the prior art teachings would have been obvious because as held in host of cases including *Ex parte Harris*, 748 O.G. 586; *In re Rosselete*, 146 USPQ 183; *In re Burgess*, 149 USPQ 355 and as exemplified by *In re Betz*, "the test of obviousness is not express suggestion of the claimed invention in any and all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them".

NEW GROUND OF REJECTION

The following is a new ground of rejection necessitated by Applicant's amendment.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "the step of" in line 1. There is insufficient antecedent basis for this limitation in claim 1 or claim 18. The above phrase has been deleted from claims 1 and 18 by the amendment filed 05/03/05. Appropriate correction is required.

ACTION IS FINAL, NECESSITATED BY AMENDMENT

5. Applicant's submission of the requirements for the joint research agreement prior art exclusion under 35 U.S.C. 103(c) on 5/3/05 prompted the new ground(s) of rejection under 37 CFR 1.109(b) presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.02(l)(3). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRSPONDANCE

6 No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CAMPELL BRUCE can be reached on (571) 272 0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohamed/AAM

July 18, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER